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Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-45

March 4, 1999

Hugo A. Ruan, Secretary/Treasurer
Ivipa Corporate, Inc.
dba Guanabo Seafood
2285 N.W. 21st Terrace
Miami, Fl 33142

Dear Mr. Ruan:

On October 6, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 2285 N.W. 21st Terrace, Miami, FL. The investigator documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the seafood products processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (The Act), as follows:

> Failure to have and implement a written HACCP plan to control the potential histamine hazard that is reasonably likely to occur with the Mahi-Mahi and other histamine forming species received, processed and distributed by your firm. [21 CFR 123.6(b)]
>
> Failure to maintain sanitation control records [21 CFR 123.11(c)] that document the monitoring and correction of sanitation conditions specified in the regulations [21 CFR 123.11(b)], for example, plant water and ice safety, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection from contaminants, proper labeling, storage, and use of toxic compounds, control of employee health conditions, and exclusion of pests.
>
> Failure to monitor the sanitation conditions and practices specified in the regulations regarding maintenance of hand washing, hand sanitizing, and toilet facilities, i.e., lack of a hand washing station in the filleting room, and no hand soap or hand dip stations provided for production employees. [21 CFR 123.11(b)(4)]

Failure to take any of the affirmative steps listed in 21 CFR 123.12(a)(2)(ii) A-F to ensure that the imported products were processed in compliance with the seafood HACCP regulation.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination and will not issue any certificates for export of any of the seafood products processed at your facility until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District